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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,003

06/05/2007

Maria Rosa Gasco

CELLTH 3.3-014

4188

530 7590 03/21/2008

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER

NAZARIO GONZALEZ, PORFIRIO

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

03/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,003	Applicant(s) GASCO ET AL.	
	Examiner PORFIRIO NAZARIO GONZALEZ	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/05/2007</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "an aqueous solution of the platinum;" is not clear since it appears to read in an aqueous solution of the metal, which is not known in the art. It is known in the art aqueous solutions of metal compounds that are soluble in water not the metal itself. Further it appears that the word "compound", that followed the above mention phrase, was deleted in the preliminary amendment filed September 25, 2006 making the claim unclear.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "heating to complete solution" at step b) is unclear as to the meaning. How you complete a solution by heating said solution? Please clarify.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 6,287,593. The '593 patent discloses lipid complexes and liposomes of highly insoluble platinum complexes, pharmaceutical compositions containing said complexes and method for treating a cancer tumor in a patient. The '593 particularly discloses diaminocyclohexane platinum-dicarboxylates as the platinum complexes. Note that said compound meets the requirements of claim 1 by having an anionic ligand (the dicarboxylate ligand) and a ligand containing amino groups (the diaminocyclohexane ligand). Further, the '593 patent discloses that the lipid complex have a particle size distribution ranging from 10 to 500 nm, which also meets the nanoparticle limitation. As for claim 3, a product-by-process claim, it's the Examiner's position that it's the product and not the process what is claimed thus the '593 patent anticipates said claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,287,593 in view of either U.S. Patent No. 6,596,889 or U.S. Patent No. 6,011,166. The '593 patent discloses lipid complexes and liposomes of highly insoluble platinum complexes, pharmaceutical compositions containing said complexes and method for treating a cancer tumor in a patient. The '593 particularly discloses diaminocyclohexane platinum-dicarboxylates as the platinum complexes. Further, the '593 patent discloses that the lipid complex have a particle size distribution ranging from 10 to 500 nm. The '593 patent disclosure differ from the instant claim 2 in the particular platinum complex used. The platinum complexes having the formulas I-V in claim 2 are dinuclear or trinuclear platinum complexes whereas the '593 patent discloses mononuclear platinum complexes. The '889 patent discloses nitrates of bis-platinum complexes with polyamine ligands also having antitumor activity and the '166 patent

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discloses trinuclear cationic platinum complexes having antitumor activity. One skilled in the art would be motivated to substitute the mononuclear platinum complex in the lipid composition of the '593 patent with either the dinuclear platinum complex of the '889 patent or the trinuclear platinum complex of the '166 patent since all of them are active against tumor cancers with the expectation that said lipid composition would also have similar activity as the '593 lipid composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PORFIRIO NAZARIO GONZALEZ whose telephone number is (571)272-0641. The examiner can normally be reached on Mon.-Fri. (9:30 AM - 6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Porfirio Nazario-Gonzalez/
Primary Examiner
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March 16, 2008